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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,525	09/08/2006	Albertus Alard Dijk	4662-228	9517

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EXAMINER	
BADR, HAMID R	
ART UNIT	PAPER NUMBER
1781	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,525	DIJK ET AL.	
	Examiner	Art Unit	
	HAMID R. BADR	1781	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *10-32* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *10-32* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' amendment filed 7/27/2011 is acknowledged.

Claims 10-32 are being considered on the merits.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 10-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

3. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Case law holds that applicant's specification must be "commensurately enabling [regarding the scope of the claims]" *Ex Parte Kung*, 17 USPQ2d 1545, 1547 (Bd. Pat. App. Inter. 1990). Otherwise **undue experimentation** would be involved in determining how to practice and use applicant's invention. The test for undue experimentation as to whether or not all compounds within the scope of claims 10-32 can be used as claimed and whether claims 10-32 meet the test is stated in *Ex parte Forman*, 230 USPQ 546, 547 (Bd. Pat. App. Inter. 1986) and *In re Wands*, 8 USPQ2d 1400, 1404 (Fed.Cir. 1988).

4. Claims10-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for adding carboxypeptidase CPD-1 to cheese, does

not reasonably provide enablement for enzyme modified cheese (EMC). An enzyme modified cheese as the name implies and as understood in the art is a cheese which has been already treated with enzymes e.g., protease or lipase to enhance or intensify the flavor. Claim 1 recites " A process for manufacturing a more matured taste in enzyme modified cheese (EMC)". However, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

5. Level of skill in the art: An enzyme modified cheese is a cheese which has already been treated with enzymes. Therefore, an additional enzyme treatment is not justified.

6. The presence of Examples: Example 7 in the specification, involves "young Gouda cheese" which is modified by incorporating carboxypeptidase. "young Gouda cheese" is not considered an EMC.

7. Level of Unpredictability: A limited showing with respect to generation of flavor in cheese or cheese milk does not grant a predictable behavior by a cheese product such as EMC when treated with carboxypeptidase.

8. For these reasons, the applicant is not entitled to a patent having such a broad scope.

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 10-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 10 is indefinite for "a more matured taste". This is a relative term. This term is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

4. Claim 14 is indefinite for "increasing the flavor intensity". This is a relative term. This term is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention, (increased over what?).

5. Claims 10, 14, 18, 28, 30, 31 and 32 are indefinite because of addressing the same concept. These claims recite processes for manufacturing more matured taste, increasing the flavor intensity, and accelerating cheese ripening which are basically the same concepts; all resulted by the addition of carboxypeptidase CPD-1 to cheese.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 10-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delest et al. (US 6,875,456, hereinafter R1) with Dal Degan et al. (1992, Purification and characterization of two serine carboxypeptidases from Aspergillus niger; cited in the specification; hereinafter R2) as evidentiary reference.

2. R1 discloses hydrolyzing a protein containing substrate with an endoprotease and an exoprotease whereby the combined action of the endoprotease and exoprotease releases at least one free amino acid from the protein containing substrate. (col. 3, lines 50-55)

3. R1 discloses that food compositions comprising protein hydrolysates of their invention obtain an improved flavor e.g. after fermentation, processing or cooking. (col. 4, lines 23-26).

4. R1 discloses that many amino acids have been indicated in the aroma development of fermented products like cheese. Hydrophobic amino acids like valine, leucine, isoleucine, phenylalanine as well as sulfur containing amino acids like methionine are known to be of particular importance. (col. 5, lines 53-58 and lines 63-67)

5. R1 discloses that the protein containing substrate may be milk proteins e.g., casein and whey proteins. (col. 6, lines 20-21)

6. R1 discloses that the endo and exo proteases employed for their protein hydrolysis are pure for at least 95% of a single proteolytic activity. (col. 7, lines 5-9)

7. R1 discloses the endoproteases which can be used including enzymes with rennet like specificity, for example microbial rennet (col. 7, lines 42-56) and preferred selective carboxypeptidase including CPD-1 of Aspergillus niger. (col. 8, lines 1-4).

8. It is noted that claim 1 requires adding carboxypeptidase CPD-1 to either cheese milk, or curd at salting stage or cheese paste. Claim 1 recites adding the exoprotease to cheese milk prior to; or together with the addition of coagulant. Microbial rennet is conventionally used in cheese making for coagulation of casein to obtain the cheese curd. Therefore, since R1 discloses the cooperative action of carboxypeptidase CPD-1 and rennet, for generation of flavor or flavor precursors, the addition of carboxypeptidase to cheese milk before adding the coagulant (rennet), or together with coagulant, or to cheese curd and cheese paste which already include the rennet coagulant would be obvious.

9. New claims 28-32 require the liberation of leucine, methionine and valine. R1 discusses the importance of these amino acids in flavor development (see paragraph 4 above). At the same time, carboxypeptidase CPD-1 of Aspergillus niger has high specificity of for these amino acids. The evidentiary reference R2 clearly discloses this specificity. R2 discloses that the highest specificity is obtained for hydrophobic residues such as leucine, methionine, valine etc. (page 2147, enzymatic properties of CPD-1 and CPD-II). Therefore, adding carboxypeptidase CPD-1 of Aspergillus niger, as disclosed by R1, will intrinsically liberate leucine, methionine and valine as presently claimed in claims 28-32.

10. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to incorporate the carboxypeptidase CPD-1 into cheese, to enhance the flavor of the cheese. One would do so to enhance the cheese flavor or accelerate the ripening of cheese. Absent any evidence to contrary and based on the teachings of the cited reference, there would be a reasonable expectation of success in enhancing the cheese flavor.

Response to Arguments

Applicants' arguments have been considered. These arguments are not deemed persuasive.

1. Applicants argue that claims 10, 14, 18, 28, 30, 31 and 32 do not convey the same concept as asserted by the Examiner.

a. These claims recite processes for manufacturing more matured taste, increasing the flavor intensity, and accelerating cheese ripening which are basically the same concepts; all resulted by the addition of carboxypeptidase CPD-1 to cheese.

2. Applicants argue that according to R1, out the list of enzymes disclosed, 85 combinations can be made.

a. The Examiner does not agree. The process is regarding cheese. The rennet (as the endoprotease) is already in cheese. The exopeptidase, i.e., the carboxypeptidase, is preferably CPD-1, CPD-II, and carboxypeptidase B, according to R1. Therefore, three carboxypeptidases were needed to be tested. No undue experimentation is required to check the 3 carboxypeptidases.

3. Applicants argue that the combination of rennet-CPD-1 is arbitrary and the effect could not be predicted.

a. Cheese contains rennet. The selection of CPD-1 out of the 3 carboxypeptidases of R1, does not involve uncertainty.

4. Applicants argue that R2 is silent regarding released amino acids when CPD-1 is combined with a coagulant.

a. R2 is an evidentiary reference. R1 clearly discloses the preferred carboxypeptidases. When cheese is the substrate, the protein is milk protein, the endoprotease is rennet. Therefore, what needed to be tested was an exopeptidase out of the three choices as disclosed by R1. This would be done by routine experimentation.

5. Applicants argue that R1 points out that the effect of a combination of enzymes in very unpredictable and that R2 cannot remedy this deficiency.

a. R1 discloses the combination of an endoprotease together with an exoprotease such as carboxypeptidase regarding a variety of protein substrates. However, when cheese is involved. The substrate, and the endoprotease (i.e., rennet) are set. The only enzyme to be focused in the exoprotease. R1 clearly suggest three enzymes one of which is the CPD-1 which is presently claimed.

b. R2 is an evidentiary reference to show that the specificity of CPD-1 for certain amino acids was known in the art before the invention was made.

Conclusion

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald Tarazano can be reached on (571) 272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. Lawrence Tarazano/
Supervisory Patent Examiner, Art Unit 1781

Hamid R Badr
Examiner
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